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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,894	04/14/2006	Katsuyuki Hamada	TSU-007	4681

38051 7590 09/29/2009

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EXAMINER
SHEN, WU CHENG WINSTON

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
09/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,894	HAMADA ET AL.	
	Examiner	Art Unit	
	WU-CHENG Winston SHEN	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,9 and 11* is/are pending in the application.

4a) Of the above claim(s) *4-7 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 3, and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/03/2009 has been entered.

Claims 1, 8, and 10 are cancelled. Claim 11 is newly added. Claims 2-7, 9, and 11 are pending. Claims 2-7 and 9 are amended.

Claims 4-7 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 2, 3, and 11 are currently under examination to the extent of elected species 1A1.3B promoter (claim 2), and adenovirus (claim 3).

This application 10/575,894 is a 371 of PCT/JP04/15221 filed on 10/15/2004, which claims the priority of JAPAN 2003-354983, filed on 10/15/2003.

Priority

2. The following statement has been documented on page 3 of the office action mailed on 09/04/2008.

This application 10/575,894 filed on 04/14/2006, the filed Oath and Declaration filed on 04/14/2006 claims benefit of foreign application Japan 2003-354983 filed on 10/15/2003. The Examiner acknowledges that Applicant has submitted on 04/14/2006 a certified copy of Japan 2003-354983 filed on 10/15/2003 under requirement of 35 U.S.C. 119 (a-d) conditions.

However, it is noted that, the application Japan 2003-354983 filed on 10/15/2003 is in Japanese. Therefore, without a certified translation of Japan 2003-354983 filed on 10/15/2003, the effective filing date for the instant claims is the filing date of PCT/JP04/15521, 10/15/2004. Applicant cannot rely upon the foreign priority papers to overcome the rejection under 35 USC 102 (e) or 102 (a), when applicable, because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 2, 3, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly added claim 11 reads as follows: A cancer gene therapeutic drug kit comprising: a tumor cell to be administrated prior to a carrier cell to induce tumor vaccination, and a carrier cell infected with an oncolytic virus, so as to make the oncolytic virus act on a tumor cell within a living body, wherein the carrier cell is a A549 cell.

Claim 11 as written is unclear in two aspects. First, the preamble "a cancer gene therapeutic drug kit" recited in claim 11 is unclear. The preamble, as written, is a compound phase of "cancer gene", "therapeutic drug" and/or "drug kit". The metes and bounds of "cancer gene" cannot be determined in the absence of clear definition provided in the specification.

Second, the phrase "to induce tumor vaccination" in the recited component of the kit "a tumor cell to be administrated prior to a carrier cell to induce tumor vaccination" is unclear because, as written, it is unclear whether "a tumor cell" or "a carrier cell" is "to induce tumor vaccination". Furthermore, the phrase "to induce tumor vaccination" is unclear because vaccination is a process to induce desired immune response. Therefore, it is the immune response against tumor cells that is induced via vaccination; the process of vaccination can be performed, not induced. Claims 2 and 3 depend from claim 11.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Previous rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Hamada et al. (Hamada et al., Identification of the human IAI.3B promoter element and its use in the construction of a replication-selective adenovirus for ovarian cancer therapy, *Cancer Res.* 63(10):2506-12, 2003), is ***withdrawn*** because independent claim 1 has been cancelled and claims

2 and 3 depend from newly added claim 11. The rejection of claim 10 is ***moot*** because claim 10 has been cancelled.

5. Previous rejection of claims 1 and 3 under 35 U.S.C. 102(b) as being anticipated by Tsukuda et al. (Tsukuda et al., An E2F-responsive replication-selective adenovirus targeted to the defective cell cycle in cancer cells: potent anti-tumoral efficacy but no toxicity to normal cell. *Cancer Res.* 62(12):3438-47, 2002; this reference is listed citation #5 on the IDS filed on 07/06/2008), is ***withdrawn*** because independent claim 1 has been cancelled and claim 3 depends from newly added claim 11. The rejection of claim 10 is ***moot*** because claim 10 has been cancelled.

6. Previous rejection of claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by **Li et al.** (US Patent 7,026,164, issued Apr. 11, 2006, filed on 07/03/2003), is ***withdrawn*** because independent claim 1 has been cancelled claim 3 depend from newly added claim 11. The rejection of claim 10 is ***moot*** because claim 10 has been cancelled.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Previous rejection of claims 1 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over **Tsukuda et al.** (Tsukuda et al., An E2F-responsive replication-selective adenovirus targeted to the defective cell cycle in cancer cells: potent anti-tumoral efficacy but no toxicity to normal cell. *Cancer Res.* 62(12):3438-47, 2002) in view of **Molnar-Kimber et al.** (Molnar-Kimber et al., WO 99/45783, international publication date, 09/16/1999), is ***moot*** because claims 1 and 8 have been cancelled.

The following new grounds of rejection under 35 U.S.C. 103(a) are necessitated by claim amendments filed on 08/03/2009.

8. Claims 2, 3, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nanni et al.** (Nanni et al., Combined allogeneic tumor cell vaccination and systemic interleukin 12 prevents mammary carcinogenesis in HER-2/neu transgenic mice, J Exp Med. 2001 Nov 5;194(9):1195-205, 2001) in view of **Hamada et al.** (Hamada et al., Identification of the human IAI.3B promoter element and its use in the construction of a replication-selective adenovirus for ovarian cancer therapy, *Cancer Res.* 63(10):2506-12, 2003; this reference has been cited in the office action mailed on 09/04/2008).

Newly added claim 11 reads as follows: A cancer gene therapeutic drug kit comprising: a tumor cell to be administrated prior to a carrier cell to induce tumor vaccination, and a carrier cell infected with an oncolytic virus, so as to make the oncolytic virus act on a tumor cell within a living body, wherein the carrier cell is a A549 cell.

Claim 2 further limits claim 11 by recitation of the oncolytic virus to be infected to the carrier cell has the 1A1.3B promoter. Claim 3 further limits claim 3 by recitation of the virus for immunological treatment and the oncolytic virus being adenovirus.

Claim interpretation: As discussed in the rejection of claims 2, 3, and 11 under 112 second paragraph, the limitations "A cancer gene therapeutic drug kit" and "a tumor cell to be administrated prior to a carrier cell to induce tumor vaccination" are unclear and can be subject to various interpretations. However, it is noted that, for prior art rejection of a product, regardless the product been called a kit, a composition or something else, the components of the product are considered for patentable weight whereas intended uses of the product, bear limited, patentable weight, if any. For claim 11, the phrases "to be administrated prior to a carrier cell to induce tumor vaccination" and "so as to make the oncolytic virus act on a tumor cell within a living body" are considered as intended uses of the claimed kit. For the same reason, the intended use "for immunological treatment" recited in line 2 of claim 3 is considered for limited patentable weight, if any. The above claim interpretations are based on MPEP 2111.03 cited below.

The intended use and inherent properties are not considered with patentable weight for the claimed composition because the components of the composition remain the same. Intended used does not impart patentable weight to a product. See MPEP 2111.03:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the

claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

With regard to a tumor cell for intended use in tumor vaccination recited in claim 11, **Nanni et al.** teaches administering allogeneic mammary carcinoma cells expressing HER-2/neu combined with systemic IL-12. This treatment reduced tumor incidence by 90% and more than doubled mouse lifetime. For the maximum prevention p185 (neu) antigen must be expressed by allogeneic cells, and IL-12 treatment strongly increased the cell vaccine efficacy (See abstract, Nanni et al., 2001).

With regard to the limitation "A549 cell" recited in claim 1, the limitation "IAI.3B promoter" recited in claim 2 and adenovirus recited in claim 3, **Hamada et al.** disclosed the following teachings : **(i)** Identification of the tissue specific promoter region of the IAI.3B gene and construction of a replication-selective adenovirus, AdE3-*IAI.3B*, driven by the promoter (See abstract and Figure 2, Hamada et al., 2003); **(ii)** The lung cancer A549 transfected with an oncolytic adenovirus Ad*E2F-1*^{RC}, and AdE3-*IAI.3B* has a construction design similar to that of the adenovirus Ad*E2F-1*^{RC}, because both have an intact *E1A* promoter upstream of their respective heterologous promoters (See Discussion, second paragraph, right column, page 2510, Hamada, 2003), and **(iii)** AdE3-*IAI.3B* replicated as efficiently as the wild-type adenovirus and caused extensive cell killing in a panel of ovarian cancer cells *in vitro*, in contrast, squamous cell carcinoma and normal cells were not able to support AdE3-*IAI.3B* replication (See abstract and Figure 3, Hamada et al., 2003), and **(iv)** In animal studies, AdE3-*IAI.3B* administered to

flank and i.p. xenografts of ovarian cancer cells led to a significant therapeutic effect (See abstract and Figure 4, Hamada et al., 2003).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Nanni et al. regarding administering allogeneic mammary carcinoma cells expressing HER-2/neu for breast cancer vaccination, with the teachings of Hamada et al. regarding identification of the human IAI.3B promoter element and its use in the construction of a replication-selective adenovirus for ovarian cancer therapy, to arrive at a kit comprising a tumor cell for tumor vaccination and the A549 cell infected with an oncolytic adenovirus for killing ovarian tumor cells, as recited in claims 2, 3, and 11 of instant application.

One having ordinary skill in the art would have been motivated to combine the teachings of Nanni et al. and Hamada et al. because there are two different molecular mechanisms underlying the treatment of breast and ovarian cancers. In this regard, Nanni et al. teaches administering allogeneic mammary carcinoma cells expressing HER-2/neu for breast cancer vaccination to enhance immune response against the cancer cells whereas Hamada et al. teaches replication-selective oncolytic adenovirus comprising by IAI.3B promoter that targets ovarian cancer specifically.

There would have been a reasonable expectation of success given (i) the immune response against breast cancer antigen HER-2/neu elicited by the administration allogeneic mammary carcinoma cells expressing HER-2/neu, by the teachings of Nanni et al., and (ii) successful demonstration of AdE3-*IAI.3B* replicated as efficiently as the wild-type adenovirus and caused extensive cell killing in a panel of ovarian cancer cells *in vitro*, in contrast, squamous

cell carcinoma and normal cells were not able to support AdE3-*IAI.3B* replication, by the teachings of Hamada et al.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

9. Claims 2, 3, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nanni et al.** (Nanni et al., Combined allogeneic tumor cell vaccination and systemic interleukin 12 prevents mammary carcinogenesis in HER-2/neu transgenic mice, J Exp Med. 2001 Nov 5;194(9):1195-205, 2001) in view of **Tsukuda et al.** (Tsukuda et al., An E2F-responsive replication-selective adenovirus targeted to the defective cell cycle in cancer cells: potent anti-tumoral efficacy but no toxicity to normal cell. *Cancer Res.* 62(12):3438-47, 2002; this reference has been cited in the office action mailed on 09/04/2008) and **Barker et al.** (Barker et al., WO 98/23779, international publication date, 06/04/1999).

Newly added claim 11 reads as follows: A cancer gene therapeutic drug kit comprising: a tumor cell to be administrated prior to a carrier cell to induce tumor vaccination, and a carrier cell infected with an oncolytic virus, so as to make the oncolytic virus act on a tumor cell within a living body, wherein the carrier cell is a A549 cell.

Claim 2 further limits claim 11 by recitation of the oncolytic virus to be infected to the carrier cell has the 1A1.3B promoter. Claim 3 further limits claim 3 by recitation of the virus for immunological treatment and the oncolytic virus being adenovirus.

Claim interpretation: As discussed in the rejection of claims 2, 3, and 11 under 112 second paragraph, the limitations "A cancer gene therapeutic drug kit" and "a tumor cell to be

administrated prior to a carrier cell to induce tumor vaccination" are unclear and can be subject to various interpretations. However, it is noted that, for prior art rejection of a product, regardless the product been called a kit, a composition or something else, the components of the product are considered for patentable weight whereas intended uses of the product, bear limited, patentable weight, if any. For claim 11, the phrases "to be administrated prior to a carrier cell to induce tumor vaccination" and "so as to make the oncolytic virus act on a tumor cell within a living body" are considered as intended uses of the claimed kit. For the same reason, the intended use "for immunological treatment" recited in line 2 of claim 3 is considered for limited patentable weight, if any. The above claim interpretations are based on MPEP 2111.03 cited below.

The intended use and inherent properties are not considered with patentable weight for the claimed composition because the components of the composition remain the same. Intended used does not impart patentable weight to a product. See MPEP 2111.03:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

With regard to a tumor cell for intended use in tumor vaccination recited in claim 11, **Nanni et al.** teaches administering allogeneic mammary carcinoma cells expressing HER-2/neu

combined with systemic IL-12. This treatment reduced tumor incidence by 90% and more than doubled mouse lifetime. For the maximum prevention p185 (neu) antigen must be expressed by allogeneic cells, and IL-12 treatment strongly increased the cell vaccine efficacy (See abstract, Nanni et al., 2001).

With regard to the limitation "A549 cell" recited in claim 1, the limitation "1A1.3B promoter" recited in claim 2, and adenovirus recited in claim 3, **Tsukuda et al.** disclosed the following teachings : **(i)** The construction of an adenovirus Ad*E2F-1*^{RC} and transfection of the Ad*E2F-1*^{RC} in A549 cells, so that E1A expression and viral replication were under the control of the human E2F-1 promoter element (See abstract and Material and Methods, left column, page 3440, Tsukuda et al., 2002); **(ii)** The Ad*E2F-1*^{RC} virus replicated as efficiently as the wild-type adenovirus and caused extensive cell killing in a panel of tumor cells (i.e. an oncolytic virus) *in vitro*, in contrast, non-proliferating normal epithelial, fibroblast, and endothelial cells, which express no E2F-1, were not able to support Ad*E2F-1*^{RC} replication (See abstract and Figures 3-5, Tsukuda et al., 2002); and **(iii)** In animal studies, different dosing regimens of Ad*E2F-1*^{RC} administered to flank xenografts of ovarian and lung cancers led to a significant therapeutic advantage often surpassing that seen in animals treated with the wild-type adenovirus (See abstract and Figures 6-7, Tsukuda et al., 2002). Furthermore, **Barker et al.** teaches IAI.3B promoter and BRCA1 promoter are involved in breast and ovarian cancer etiology (See abstract and Example 4 on pages 19-20, Baker et al., 1998). It is noted that replacing E2F promoter taught by Tsukuda et al. with the IAI.3B promoter taught by Baker et al. would result in tissue specificity infection of the adenovirus with reasonable expectation of

success because swapping promoters to achieve tissue specific expression of a gene of interest is a well-established molecular technique to a skilled artisan.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Nanni et al. regarding administering allogeneic mammary carcinoma cells expressing HER-2/neu for breast cancer vaccination, with the teachings of Tsukuda et al. regarding administration of A459 cells infected with mutated oncolytic adenovirus Ad*E2F-1*^{RC} results to killing of variety of cancer cells, and the teachings of Baker et al. regarding involvement of IAI.3B promoter is involved in breast and ovarian cancer etiology, to arrive at a kit comprising a tumor cell for tumor vaccination and the A549 cell infected with an oncolytic adenovirus for killing tumor cells, as recited in claims 2, 3, and 11 of instant application.

One having ordinary skill in the art would have been motivated to combine the teachings of Nanni et al., Hamada et al., and Barker et al. because there are two different molecular mechanisms involved in treating breast and ovarian cancer etiology. In this regard, Nanni et al. teaches administering allogeneic mammary carcinoma cells expressing HER-2/neu for breast cancer vaccination to enhance immune response against the cancer cells whereas combined teachings of Tsukuda et al. and Baker et al. teach replication-selective oncolytic adenovirus comprising the IAI.3B promoter that targets ovarian cancer specifically.

There would have been a reasonable expectation of success given (i) the immune response against breast cancer antigen HER-2/neu elicited by the administration allogeneic mammary carcinoma cells expressing HER-2/neu, by the teachings of Nanni et al., and (ii) successful demonstration of treating cancer cells A459 cells infected with replication-selective

oncolytic adenovirus Ad*E2F-1*^{RC} leads to potent anti-tumoral efficacy but no toxicity to normal cells by the teachings of Tsukuda et al., and (iii) the disclosure of IAI.3B promoter being active specifically in breast cancer and ovarian cancer cells, by the teachings of Barker et al.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Applicant's arguments

Applicant's remarks filed on 08/03/2009 regarding the previous rejection of record are addressed as the related to the new grounds of rejection set forth above. Related posting filing publications filed by Applicant as Appendix I-IV on 08/03/2009 have been considered along with Applicant's remarks.

Applicant argues that none of the cited references would make it obvious for a person skilled in the art to try using A549 cells as the carrier cell, and the references are silent about the unexpected excellent effects achieved by the use of A549 cells. A skilled artisan would not have been able to select a cell line that achieves remarkable anti-tumor effects among various cells that are usable as the carrier cell, and use such a cell line in treating cancer, in combination with the administration of tumor cells to induce tumor vaccination, based on the disclosures of the cited references (See page 7 of Applicant's remarks filed on 08/03/2009).

In response, the effect of A549 as a carrier cell infected with oncolytic adenovirus with E1A gene under the control of IAI.3B promoter are taught in the prior arts by either Hamada et al. or by combined teachings of Tsukuda et al and Barker et al., which are elaborated in the 103 rejections documented in this office action. In this regard, the posting filing publications submitted as Appendix I (Figure 1), Appendix III (Wei et al. 2007, pertaining to oncolytic

measles virus), and Appendix IV (Hakkarainen et al., 2007; pertaining to oncolytic adenovirus enhanced by human mesenchymal stem cell), and related prior art Appendix II (Coukos et al., 1999, pertaining to oncolytic HSV) filed by Applicant on 08/03/2009 further support this finding. Accordingly, the status of art clearly established the use of A549 cells transfected with oncolytic virus in treating breast or ovarian cancers. Therefore, the arguments about the unexpected excellent effects achieved by the use of A549 cells have been fully considered and found not persuasive.

Conclusion

10. No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, Jr. can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Wu-Cheng Winston Shen/
Patent Examiner
Art Unit 1632